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Dkt. 0640/71348/JPW/AG

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Janaswamy Madhusudana Rao et al.

Serial No.: 10/695,471

Filed : October 28, 2003

For : A NOVEL HERBAL COMPOSITION FOR THE TREATMENT OF
GASTRIC ULCER

1185 Avenue of the Americas
New York, New York 10036
April 21, 2005

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**COMMUNICATION IN RESPONSE TO FEBRUARY 25, 2005
OFFICE ACTION AND PETITION FOR ONE-MONTH EXTENSION OF TIME**

This Communication is submitted in response to the Office Action issued by the U.S. Patent and Trademark Office on February 25, 2005 in connection with the above-identified application. A response to the February 25, 2005 Office Action was originally due March 25, 2005. Applicants hereby petition for a one-month extension of time. The fee for a one-month extension of time is one hundred and twenty dollars (\$120.00) and a check for this amount is enclosed. A response to the February 25, 2005 Office Action is now due on April 25, 2005. Therefore, this Communication is being timely filed.

In the February 25, 2005 Office Action, the Examiner required restriction to one of the following allegedly independent and distinct inventions characterized by the following Groups I-V:

I. Group I, claims 1-12, drawn to a composition for the treatment of gastric ulcer essentially comprising claim-designated powdered plant parts and optionally powder plant parts of claim-designated plants, classified in class 424,

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Subclass 744 or 757 or 725;

II. Group II, claims 13-24, drawn to a composition for the treatment of gastric ulcer comprising equal proportions of 10 powdered plant parts selected from a recited Markush group, classified in class 424, Subclass 725;

III. Group III, claims 25-36, drawn to a process for the preparation of a composition for the treatment of gastric ulcer comprising the steps of powdering plant parts essentially selected from a first recited Markush group, and optionally selected from a second recited Markush group, classified in class 424, subclass 725;

IV. Group IV, claims 37-47, drawn to a method of treating gastric ulcer comprising administering an effective amount of a composition essentially comprising powder plants of claim-designated plants, and optionally powdered plants of claim-designated plants, classified in class 514, subclass 925; and

V. Group V, claim 48, drawn to a method of treating gastric ulcer comprising administering an effective amount of a composition comprising equal proportions of 10 powdered plant parts selected from a recited Markush group, and optionally, classified in class 514, subclass 925.

In addition, the Examiner alleged that the application contains claims directed to the following patentably distinct species of the claimed invention: the distinct and separate ingredients of claim 1, namely the optional ingredients that may further comprise the claim-designated composition; and, the distinct and

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separated ingredients of claim 3.

The Examiner indicated that if applicants elect Group I, II, IV, or V, applicants are required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable. The Examiner stated that, in other words, if applicants elect Group I, applicants are required to distinctly and clearly enumerate and name the optional powdered plants comprising the claim-designated composition; if applicants elect Group II, applicants are required to distinctly and clearly enumerate and name the ten powdered plants comprising the claim-designated composition; if applicants elect Group IV, applicants are required to distinctly and clearly enumerate and name the optional powdered plants comprising the claim-designated composition used in the claimed method of treatment; or if applicants elect Group V, applicants are required to distinctly and clearly enumerate and name the ten powdered plants comprising the claim-designated composition used in the claimed method of treatment. However, the Examiner also indicates that upon allowance of a generic claim, applicants will be entitled to consideration of claims to additional species which are written in dependent form or other wise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §1.141. The Examiner further indicated that currently, claims 42-47 are generic.

In response to this restriction requirement, applicants hereby elect, with traverse, Group I, claims 1-12. Applicants also elect, with traverse, *Cyclea peltata* as the single disclosed species for prosecution at this time.

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On page 3-4 of the February 25, 2005 Office Action, the Examiner alleged that the inventions are distinct, each from the other because of the following reasons:

The Examiner alleged that the inventions of Groups I-II and IV-V are related as product and process of use. Citing M.P.E.P. §806.05(h), the Examiner states that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. The Examiner alleged that in the instant case, the process for using the product as claimed can be practiced with another materially different product, as evidenced by the teachings of Hara et al. in U.S. Patent No. 4,913,909 A.

The Examiner alleged that the inventions of Groups I-II and III are related as process of making and product made. The Examiner alleged that the inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process. The Examiner alleged that in the instant case, the process as claimed has been shown to be useful in the making of numerous materially different products, as evidenced by the claims themselves.

The Examiner alleged that inventions of Group I and II are unrelated. The Examiner alleged that inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. The Examiner further stated

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that in the instant case the two different groups are directed to two different inventions. The Examiner stated that for instance, the invention of Group I is directed to a composition comprising powdered plant parts of five designated plants and optionally comprising powdered plants of seven different designated plants, whereas the invention of Group II is directed to a composition comprising equal proportions of ten powdered plants parts from a recited Markush group of eleven claim-designated plants. The Examiner stated that different compositions comprising different ingredients in different amounts and from different plant source materials do not necessarily have the same functional effect; and, that it is generally assumed that different compositions comprising different ingredients in different amounts and from different plant source materials do not necessarily have the same functional effect.

The Examiner therefore concluded that because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes is proper.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement and species election requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application.

Applicants note that in the February 25, 2005 Office Action, the Examiner has not maintained that the claims of any of the cited Groups are independent from the claims of any other cited Groups.

Applicants maintain that the inventions of the cited groups are

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not independent. Under MPEP §802.01, "[t]he term 'independent' means there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect". Groups I and II claim compositions for the treatment of gastric ulcer. Group III claims the method of making such compositions. Groups IV and V claim methods of using such compositions for treating gastric ulcers. Groups I-V are necessarily related because the process of Group III produces the compositions of Groups I and II which are required to practice the methods of Groups IV and V. In fact, on page 3 of the Office Action, the Examiner has in effect acknowledged the above, i.e. that the claims of Groups I-II and the claims of Groups IV-V are not independent, as they are related as product and process of use, and that the claims of Groups I-II and the claims of Group III are not independent as they are related as process of making and product made. Furthermore, applicants maintain that the claims of Group I and the claims of Group II have the same mode of operation, the same function, and the same effects.

In addition, applicants point out that M.P.E.P. §806.05(f) cited by the Examiner, fails to support restriction. Applicants note that the examiner misstates the test for restriction under M.P.E.P. §806.05(f), which states that a "process of making and a product made by the process can be shown to be distinct inventions if either or both of the following can be shown: (A) that the process as *claimed* is not an obvious process of making the product and the process as *claimed* can be used to make other and different products; or (B) that the product as *claimed* can be made by another and materially different process." (emphasis in original.) Specifically, restriction on the basis of subsection (A), as relied upon by the Examiner, requires both that the process as claimed is not an obvious process of making the product and that the process as claimed can be used to make other and different products. The Examiner includes only the latter

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requirement in the statement of the test in the February 25, 2005 Office Action.

Applicants also note that on page 4 of the February 25, 2005 Office Action, the text quoted by the Examiner, supports the applicants' argument against restriction. It states:

[w]here applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier."

This means that if applicants elect the product, which they are doing, they are entitled to have the process claims examined. Therefore, the claims in Group I and II (product) and Group III (process of making the product) should be examined together. Restriction, in these circumstances, is not proper.

Applicants further note that M.P.E.P. §803 unambiguously provides that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction is not required between Groups I-IV because a search of the prior art relevant to any of the claims of any of the Groups would necessarily turn up the prior art relevant to the claims of the remaining Groups. There is therefore no burden on the Examiner to examine Groups I and II together in the subject application, and applicants submit that the Examiner must examine the entire application on the merits.

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In view of the foregoing, applicants maintain that the February 25, 2005 restriction requirement is not proper under 35 U.S.C. § 121 and respectfully request that the Examiner reconsider and withdraw the requirement.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the \$120.00 extension fee, is deemed necessary in connection with the filing of this Communication. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

John P. White 4/21/05
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